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| 10/019,166 | 02/28/2002 | Meinhard Knoll | SPM-339-A | 6240 |
| | 7590 | 02/12/2004 | EXAMINER | |
| Andrew R Basile Young & Basile 3001 West Big Beaver Road Suite 624 Troy, MI 48084 | | | OLSEN, KAJ K | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1753 | |

DATE MAILED: 02/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/019,166

Applicant(s)

KNOLL, MEINHARD

Examiner

Kaj Olsen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5-10-2002.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: The chemical compound --KCl-- appears to be mistyped at various points through the specification. In paragraphs 0039 and 0045 on pages 8 and 10 respectively, it is written as "KCl".
2. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. In the claims, applicant utilizes the terms "orientated away" or "orientated toward", but it is unclear how applicant wishes these terms to be interpreted. The ordinary meaning of the term "orientated" followed by "toward" or "away" would be as a sense of direction and specifying that something is either orientated toward or away from something else would appear to indicate that the something either faces or points in one direction or another. However, in claim 1 where an opening extends through the two carrier layers, how is one of the openings considered "orientated away" while the other is "orientated towards" the first active surface? Both of these openings could reasonably be construed as either pointing towards or away from the first active surface layer and assigning a sense of direction to these two openings that are opposite each

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other appears to be arbitrary. What is the applicant's criteria for assigning a sense of direction?

The examiner recommends the applicant instead define these openings not based on sense of direction, but instead on relative placement of the various openings with respect to other defined elements of the claim.

6. Claims 6 and 13 also utilize this confusing language.

7. Claim 6 is further confusing because is unclear what the "which" is referring to. What is "orientated away" from the first active surface? Furthermore, it is unclear how to interpret "at least one electrically conductive layer respectively" is referring to. In particular, what is the respectively referring to? Applicant specifies a singular conductive layer at an unspecified respective number of locations.

8. In claim 8, it is unclear what opening the applicant is referring to. Claim 1 specified two openings.

9. Claim 9 specifies a "further membrane" but claim 1 never specified a membrane making it unclear what the "further" refers to.

10. Regarding claims 9, 17-20, 23, and 24, the phrases "for example", "such as", "preferably" render the claims indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

11. In claims 10, 17, 19, 21, and 24, applicant utilizes ranges that are too vaguely defined. What would one possessing ordinary skill in the art reasonably interpret as being a "few" or "some" microns or mm?

12. In claims 11, 18, 22, and 24, applicant does not utilize appropriate alternative language for defining from a list of materials.

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13. In claim 18, one of the choices in the list is "or others" which is entirely too vague. This claim should also make it clearer that the material contains either plastic materials or silicon, ceramic or glass. Currently, it appears that silicon, ceramic, and glass are part of the list of plastic materials to be utilized.

14. In claim 22, it is unclear how to interpret "or the like".

15. In claim 25, it is unclear if the third conductive layer is required for the claim.

16. In claim 26, the limitation "forms a potentiometric electrode" is entirely too vague.

Apparatus claims should be drawn to what the electrode is and not what it does.

17. Claims 27 and 28 provide for the use of device of claim 1, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

18. In claim 28, the use of "other parameters" is vague.

19. Claims 27 and 28 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

20. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

21. Claims 1-8, 11, 13-15, 18-20, 22, 24, 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Knoll (USP 5,393,401).

22. With respect to the claims as best understood, Knoll '401 discloses a sensor for determining substance concentrations comprising a carrier 1, at least one opening 6 that extends through the carrier that defines a cavity that extends through the carrier with a filling 7 disposed in the cavity. See figure 6 and col. 5, lines 52 through col. 6, line 47. Knoll '401 further discloses a electrically conductive layer 16 in contact with the filling. See fig. 4 and 7-10 and col. 7, lines 1-13. The narrow portion of the opening 6 defines a first active surface for the sensor and the opening in the carrier layer away from the first active layer is greater than the opening at the first active layer. See fig. 12. With respect to the sensor comprising first and second carrier layers, Knoll '401 discloses that carrier 1 can be made with other layers as well such as layers 18, 21 or 22. See fig. 3 and 5, col. 6, lines 58-64, and col. 7, lines 36-54.

Alternatively, Knoll '401 also discloses that the carrier 1 is coated with a dielectric layer 15 (col. 7, lines 60-68). Any of these additional layers of Knoll '401 would read on the applicant's broadly defined first and second carrier layers (or "further flat carrier layers") giving the claim language its broadest reasonable interpretation. With respect to the term "universal transducer", unless the applicant clearly defines structure that breathes meaning into said term, that is considered only the intended use of the apparatus and the intended use need not be given further due consideration in determining patentability.

23. With respect to the content of the filling, see col. 8, lines 1-30.

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24. With respect to claim 6 as best understood, the conductive layer of Knoll '401 extends on all the layers of the carrier and this would appear to read on this claim.
25. With respect to the encapsulation, see col. 6, lines 49-57.
26. With respect to use of different fillings, see fig. 7-9 and col. 8, lines 37-44.
27. With respect to the thickness for the carrier layers or diameter for the openings, see col. 5, lines 53-55 and col. 6, lines 5-8.

Claim Rejections - 35 USC § 103

28. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

29. Claims 9, 10, 25, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knoll '401 in view of Madou et al (USP 4,874,500).
30. With respect to claims 9 and 10, Knoll '401 sets forth all the limitations of the claims, but did not explicitly recite the use of a further membrane over the first active surface. Madou discloses in an alternate sensor that a further membrane (i.e. a barrier) can be placed over the sensor so as to further restrict sample access to the sensor structure providing greater protection against interferents. See col. 10, line 11 through col. 11, lines 8. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Madou for the sensor of Knoll '401 to protect the sensor against interferents.

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31. With respect to claims 25 and 26, Knoll '401 sets forth all the limitations of the claims, but did not explicitly disclose the additional conductive layers in other cavities. Madou shows that the various electrodes needed for the sensor can be provided in nearby cavities (fig. 1 and 2). Said configuration provides a compact sensor where all the electrodes are a well defined distance apart and it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Madou for the sensor of Knoll '401 in order to provide a miniaturized sensor.

32. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Knoll '401 and Madou as applied to claim 9 above, and further in view of DE 196 02 861 A1.

33. Claims 21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE '861.

34. With respect to claim 12, the references set forth all the limitations of the claim but did not explicitly specify placing an electrically conductive layer between the further membrane and the active surface layer. However, DE '861 teaches that such a configuration is a known arrangement for the various components of the sensor (compare fig. 4 with the embodiment of fig. 9). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the embodiment of DE '861 for the sensor of Knoll '401 and Madou because the substitution of one known electrode arrangement for another requires only routine skill in the art.

35. With respect to claims 21 and 23, Knoll '401 either does not specify the conductive layer thickness or the use of biocomponents. DE '861 taught both of those aspects (see claim 11 and col. 7, lines 43-50 respectively). It would have been obvious to one of ordinary skill in the art at

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the time the invention was being made to utilize the teaching of DE '861 for the sensor of Knoll '401 in order to extend the utility of the sensor to other analytes such as bioanalytes and because the use of known electrode thicknesses requires only routine skill in the art.

36. Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knoll '401 in view of Knoll (USP 5,846,392).

37. Knoll '401 set forth all the limitations of the claim, but did not explicitly recite the presence of the specified flow channel. Knoll '392 teaches the presence of flow channel that brings various samples to the sensor structure that allows the analysis of the sample to be greater controlled (fig. 1-3 and col. 3, lines 6-44). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Knoll '392 for the sensor of Knoll '401 in order to better control how the sample interacts with the various sensor electrodes.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (571) 272-1344. The examiner can normally be reached on Monday through Thursday from 7:00 A.M. to 4:30 P.M. and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Kaj Olsen', with a stylized flourish extending from the end.

Kaj Olsen Ph.D.
Primary Examiner
AU 1753
February 9, 2004